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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,179	10/23/2003	Nael A. Al-Abdulla	58443 (71699)	2620
21874	7590	03/23/2006		
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER KIDWELL, MICHELE M	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 03/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/693,179

Applicant(s)

AL-ABDULLA ET AL.

Examiner

Michele Kidwell

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/23/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 – 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claims 30 and 31, the applicant recites a pressure-responsive valve. The independent claim upon which claims 30 and 31 depend only recite a delivery mechanism. Is the pressure responsive valve comparative to the delivery mechanism? Does the device contain a delivery mechanism in addition to a pressure-responsive valve?

Claims 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36 refers to the method of claim 30. However, claim 30 is not a method claim. It is unclear what the applicant intends to claim as an invention.

Where the metes and bounds of a claim are indefinite, it is improper to base a rejection on speculation as to the meaning of the claim. In re Steele, 305 F.2d 858, 134

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USPQ 292 (CCPA 1962). Specifically, unclear claims are indefinite, not obvious. In re Wilson, 424 F.2d 1382, 185 USPQ 494 (CCPA 1970).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 9, 11, 18 – 29, 35 – 35 and 38 – 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Berke (US 6,336,917).

With respect to claim 1, Berke discloses a device for the delivery of a substance to the eye comprising: a housing for holding the substance; at least one outlet port through which the substance is delivered from the device to the eye; and a non-aerosol, non-electric delivery mechanism, whereby the substance is delivered to the eye in the form of a spray or mist as set forth in col. 6, lines 34 – 45 and in figure 4.

Regarding claim 2, Berke discloses a device for the delivery of an artificial tears or demulcent composition to the eye comprising: a housing for holding the substance; at least one outlet port through which the substance is delivered from the device to the eye; and a non-aerosol, non-electric delivery mechanism, whereby the substance is delivered to the eye in the form of a spray or mist as set forth in the abstract, in col. 6, lines 34 – 45 and in figure 4.

With reference to claim 3, Berke discloses a device wherein the force of the spray or mist is sufficient to deliver the spray or mist to the eye without the aid of gravity as set forth in col. 6, lines 38 – 45. The examiner contends that the force is directly related to the amount of pressure applied and may be sufficient to deliver to deliver the spray or mist without the aid of gravity.

With respect to claim 4, Berke discloses a device wherein the spray is delivered to the eye in a substantially horizontal direction as set forth in figure 4.

As to claim 5, Berke discloses a device wherein the housing is hollow and the substance is contained within the hollow of the housing as set forth in figure 4.

As to claim 6, Berke discloses a device wherein the device further comprises a tubular member extending inside the hollow of the housing, thereby providing fluid communication between the outlet port and the substance within the housing as set forth in figure 4.

Regarding claim 7, Berke discloses a device wherein the housing contains a reservoir that holds the substance as set forth in figure 4.

As to claim 8, Berke discloses a device wherein the housing is fabricated of a rigid material to prevent collapse of the housing during use as set forth in col. 5, lines 44 – 46.

Regarding claim 9, Berke discloses a device wherein the housing is hollow and walls forming the housing have a thickness sufficient to prevent collapse of the housing during use as set forth in figure 4.

With reference to claim 11, Berke discloses a device wherein the housing is cylindrical in shape as set forth in figure 4..

As to claim 18, Burke discloses a device further comprising an actuation mechanism in connection with the delivery mechanism wherein manipulation of the actuation mechanism delivers the substance to the eye as set forth in col. 6, lines 38 – 40.

Regarding claims 19 and 20, Burke discloses a device wherein the actuation mechanism is movable with respect to the housing in order to deliver the substance to the eye as set forth in col. 6, lines 38 – 40. The examiner contends that the manner by which the actuation mechanism is moved is considered a product-by-process limitation that does not patentably distinguish the claimed invention from the prior art.

As to claim 21, Burke discloses a device wherein the actuation mechanism includes a spray nozzle (62) as set forth in col. 6, lines 38 – 40.

With reference to claims 22 – 23, see the rejection of claims 19 – 21.

Regarding claims 24 – 27, see col. 6, lines 38 – 45.

As to claims 28 – 29 and 32, the examiner contends that Berke discloses the invention as claimed.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The invention of Burke is fully capable of performing the recited function.

With reference to claim 33, Burke discloses a device further comprising an extension (32) substantially or completely surrounding the outlet port and extending in the direction that the spray or mist is delivered wherein the extension assists in directing the substance to the eye and assists in preventing the substance from being delivered to areas outside of the eye as set forth in figure 4.

As to claim 34, see the rejection of claim 3.

As to claim 35, see the rejection of claim 2.

As to claim 38, see the rejection of claim 4.

With reference to claims 39 – 41, see the rejection of claims 19 – 20.

As to claim 42, see col. 6, lines 38 – 40

With reference to claim 43, see the rejection of claim 27.

With reference to claims 44 – 47, see the rejection of claims 28 – 29 and 32.

As to claim 48, see col. 6, lines 33 – 45.

Regarding claims 49 – 50, see the rejection of claims 1 and 2.

As to claims 51 and 52, the examiner contends that any device may be considered reusable and/or disposable.

With reference to claims 53 and 55 – 56 , see col. 6, lines 13 – 15.

As to claim 54, the examiner contends that Berke is fully capable of performing the recited function.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 12 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke (US 6,336,917).

The difference between Burke and claim 10 is the provision that the housing is fabricated of a translucent material.

It would have been obvious to one of ordinary skill in the art to fabricate the housing out a translucent material since it is well known in the art to provide medications dispensers in translucent packaging in order to monitor the amount of product used.

The difference between Burke and claims 12 – 17 is the provision that the housing has specific dimensions.

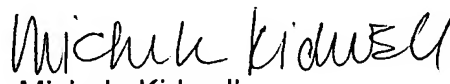


It would have been obvious to one of ordinary skill in the art to modify the dimensions of Burke to determine the most effective product since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum value involves only a level of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michele Kidwell  
Primary Examiner  
Art Unit 3761